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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,380	02/28/2002	Daniel G. Chain	P-4815-US1	3496

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,380	CHAIN, DANIEL G.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16-20,22-25,51,52,55,56,59,60,63,64,67,68,71 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 16-20, 22-25, 51-52, 55-56, 59-60, 63-64, 67-68, 71 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

2. The amendment to the claims filed on August 10, 2005 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003 (see *68 Fed. Reg. 38611,* Jun. 30, 2003) with respect to claim 69, which is not present within the text of the claim amendment. Appropriate correction is required.

Response to Amendment

3. Claims 14, 20, 51, 52, 55, 56, 59, 60, 63, 64, 67, 68, 71 and 72 have been amended and claims 1-13, 15, 21, 26-50, 53-54, 57-58, 61-62, 65-66, 69 and 70 have been cancelled as requested in the amendment filed on August 10, 2005. Following the amendment, claims 14, 16-20, 22-25, 51-52, 55-56, 59-60, 63-64, 67-68, 71 and 72 are pending in the instant application.

Claims 14, 16-20, 22-25, 51-52, 55-56, 59-60, 63-64, 67-68, 71 and 72 are under examination in the instant office action.

4. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

6. Applicant's amendment filed on August 10, 2005 necessitated the new ground(s) of rejection set forth below.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 14, 16-20, 22-25, 51-52, 55-56, 59-60 and 67-68, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk, 1999 (WO 99/27944).

Claims 14, 16-20, 22-25, 51-52, 55-56, 59-60 and 67-68 are directed to methods of inhibiting the accumulation or neurotoxicity of an amyloid β (Aβ) in the brain of a subject by administration of an antibody to Aβ. Document of Schenk discloses methods for treatment of amyloidogenic diseases (diseases that are characterized by amyloid beta deposition and neurotoxicity, see abstract and pages 1 and 13, for example) by administration of an antibody to Aβ peptide (see abstract and bottom at page 13). Further, document of Schenk specifically discloses antibodies to Aβ that could be used for administration. Such antibodies include antibodies to Aβ (bottom at page 17), monoclonal, humanized (page 18), chimeric and Fv or F(ab) antibodies (page 19). Moreover, fragments of Aβ peptide, as recited by Schenk include N- and C-terminus truncated peptides (page 15); therefore, document of Schenk fully discloses treatment by administration of antibodies to these specific fragments.

With respect to claims 51-52, 55-56, 59-60 and 67-68 directed to methods of using free-end specific antibodies, Applicant is advised that in view of the limitation "fragment thereof" or "amyloid β fragment", the recited antibody by broadest reasonable interpretation meets the limitations of any antibody to Aβ.

Thus, document of Schenk fully anticipates the instant claims 14, 16-20, 22-25, 51-52, 55-56, 59-60 and 67-68.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 63-64 and 71-72, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Schenk, 1999 (WO 99/27944) as applied to claims 14, 16-20, 22-25, 51-52, 55-56, 59-60 and 67-68 above, and further in view of Suzuki et al., 1998 (US Patent 5,750,349, issued 05/12/1998).

Claims 63-64 and 71-72 are directed to methods of inhibiting the accumulation or neurotoxicity of an amyloid β (Aβ) in the brain of a subject by administration of an antibody to Aβ, which is free-end specific and targeted to C-terminus of amyloid β 1-39 to 43. Document of

Schenk teaches administration of Aβ specific antibodies for the treatment of Alzheimer's disease, which is characterized by amyloid accumulation and neurotoxicity. Schenk does not expressly disclose administration of free-end specific antibodies directed to C-terminus of amyloid β.

Suzuki et al. disclose C-terminus specific antibodies to Aβ 1-39 to 1-43 (see claim 1 and entire document). At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to use antibodies disclosed by Suzuki et al. for a method of inhibition of Aβ accumulation and neurotoxicity, as disclosed by document of Schenk. One of ordinary skill in the art would have been motivated to do this because the art clearly teaches Aβ peptide of 1-39 to 1-43 length as the amyloidogenic substrate, which leads to the progression of Alzheimer's disease. The disclosure of Schenk postulates the principle of removal of Aβ by means of administration of antibodies specific to Aβ, thus obliterating amyloid plaque formation which occurs during Alzheimer's pathology. It would have been be obvious for a person of ordinary skill in the art that antibodies that are C-terminal-specific would provide the best specific binding to the particular amyloidogenic fragments of Aβ.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.

Primary Examiner
Art Unit 1649

September 27, 2005